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510(K) SUMMARY
W.O.M. Laser U100

DEC 11 2002

I. Submitter:

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

II. Device Names:

1.	Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology, and Electrohydraulic Lithothripter
2.	Common or Usual Name:	Intracorporal Laser Lithotripter in Urology and Gastroenterology
3.	Proprietary Name:	W.O.M. Laser U100

III. Classification:

Class II. This device is described in 21 CFR. §§ 878.4810 and 876.4480. The product code for the device is GEX, FFK.

IV. Predicate Devices:

- **W.O.M. Laser U100** (K011175) manufactured by W.O.M. WORLD OF MEDICINE AG
- **Candela MDL-2000 Laser LithoTripter** (K901723) manufactured by Candela Laser Corporation.

V. Intended Use and Indication for Use:

- The W.O.M. Laser U100 is intended for use in endoscopic surgical procedures to fragment stones.

- The W.O.M. Laser U100 is indicated for use to fragment urinary stones (kidney, ureter and bladder) and biliary stones in the contact mode during closed surgical procedures.

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VI. Technical Characteristics and Substantial Equivalence:

The W.O.M. Laser U100 has the same intended use, identical design features and principles of operation as the predicate device W.O.M. Laser U100 (K011175). Differently to the predicate device the W.O.M. Laser U100 described in this premarket notification is not only indicated for use to fragment urinary stones but also biliary stones. In addition, the W.O.M. Laser U100 has the same intended use and indication for use, similar design features and similar principles of operation as the Candela MDL 2000 LaserTripter (K901723).

All three devices are intended for use in endoscopic surgical procedures to fragment stones. Both the W.O.M. Laser U100 and the Candela MDL 2000 LaserTripter are indicated for use to fragment urinary and biliary stones in the contact mode during closed surgical procedures.

The W.O.M. Laser U100 and the predicate device W.O.M. Laser U100 (K011175) use identical physical processes to generate the laser beams and method of transmission to the stone. Although the W.O.M. Laser U100 and the Candela MDL 2000 LaserTripter (K901723) generate their respective laser beams through different physical processes, the characteristics of the treatment beams (wavelength, pulse energy, pulse duration and pulse frequency) are similar. Moreover, the method of transmission to the stone (laser fiber) is similar and both devices provide aiming beams to allow visual indication of the stone location.

All three devices incorporate an internal water cooling cycle with a water-air heat exchanger system. In addition, all three devices provide identical or similar safety features and identical or similar parameters are displayed on the operator panel of the devices.

Finally, the W.O.M. Laser U100 and the predicate devices transmit pulses of laser energy by a quartz fiber to the stone (contact mode). The laser pulses are transformed into an ultrasonic wave (acoustic impact waves) which mechanically crush the stone.

The differences of the W.O.M. Laser U100 to the predicate device W.O.M. Laser U100 (K011175) are minor and raise no new questions of safety and effectiveness. Most of the modifications rather have been made to fulfill the UL Standard 2601.

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VII. Safety and Effectiveness Information:

In vitro, in vivo and clinical data has been provided to demonstrate that the W.O.M. Laser U100 is safe and effective for the fragmentation of biliary stones in closed surgical procedures.

The device complies with the International Standard IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). In addition, the device meets the requirements of the Underwriter Laboratories Standard UL 2601-1 and bears the CE mark in accordance with the Medical Device Directive 93/42/EEC.

VIII. Conclusion:

The W.O.M. Laser U100 has the same intended use, identical design features and principles of operation as the predicate device W.O.M. Laser U100 (K011175). Moreover, the W.O.M. Laser U100 has the same intended use and indication for use, similar design features and similar principles of operation as the Candela MDL 2000 LaserTripter (K901723). The differences of the W.O.M. Laser U100 to the predicate device W.O.M. Laser U100 (K011175) are minor and raise no new questions of safety and effectiveness. Finally, in vitro, in vivo and clinical study results demonstrate that the W.O.M. Laser U100 is safe and effective for the fragmentation of biliary stones in closed surgical procedures.

Accordingly, W.O.M. WORLD OF MEDICINE AG believes that the W.O.M. Laser U100 is substantially equivalent to the W.O.M. Laser U100 (K011175) and the Candela MDL 200 LaserTripter (K901723).

Signed: S. Raab

Susanne Raab
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2002

World of Medicine
c/o Ms. Susanne Raab
91 Towbridge Street, #21
Cambridge, Massachusetts 02138

Re: K023041
Trade/Device Name: W.O.M. Laser U100
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 30, 2002
Received: September 12, 2002

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: W.O.M. WORLD OF MEDICINE AG

510(K) NUMBER (if known): K023041

DEVICE NAME: W.O.M. Laser U100

INDICATIONS FOR USE:

The W.O.M. Laser U100 is indicated for use in the contact mode to fragment urinary stones (kidney, ureter, bladder) and biliary stones in closed surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023041